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Estimation of Numbers of Testing Personnel and Test Volume in the Clinical Laboratory Improvement Amendments of 1988 Certificate of Accreditation and Certificate of Compliance Laboratories in the United States

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Abstract

Context.—Two major categories of laboratories performing nonwaived testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) are the Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) laboratories. Accreditation organizations collect more detailed laboratory personnel information than the Centers for Medicare & Medicaid Services (CMS) Quality Improvement and Evaluation System (QIES).

Objective.—To estimate total numbers of testing personnel and testing volumes in CoA and CoC laboratories, by laboratory type and state.

Design.—We developed a statistical inference method by using the respective correlations between testing personnel counts and test volume by laboratory type.

Results.—QIES reported 33 033 active CoA and CoC laboratories in July 2021. We estimated testing personnel to be 328 000 (95% CI, 309 000–348 000), which is supported by the count of 318 780 reported by the US Bureau of Labor Statistics. There were twice as many testing personnel in hospital laboratories as in independent laboratories (158 778 versus 74 904, $P <$

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.001). Independent laboratories had the highest test volume per person, which was twice as high as physician office laboratories (62 228 versus 30 102, $P < .001$). Hospital and independent laboratories comprised 34% of all CoA and CoC laboratories but performed the largest portion of testing (81%). Physician office laboratories, accounting for 44% of all CoA and CoC laboratories, performed a comparatively low proportion of total tests (9%).

Conclusions.—Numbers of testing personnel vary considerably by laboratory type and across states. These data can provide valuable insight when assessing laboratory workforce training needs and planning for public health emergencies.

Clinical laboratory testing plays a critical role in health care, public health surveillance, and emergency response. A detailed study by the Lewin Group for the Centers for Disease Control and Prevention concluded clinical laboratory testing has a major effect on clinical decisions, providing physicians, nurses, and other health care providers with information that aids in the prevention, diagnosis, treatment, and management of disease.¹ Clinical laboratories are present in all sizes and settings, ranging from small physician office laboratories to large reference laboratories, and from independent practices to academic medical centers and hospitals. The testing performed in these settings varies in complexity from Clinical Laboratory Improvement Amendments of 1988 (CLIA)–waived testing often performed at the point of care to high-complexity genetic sequencing. In 1988, Congress passed the Clinical Laboratory Improvement Amendments law² to ensure the quality of all clinical laboratory testing performed on US citizens, and the regulations implementing CLIA were published and became effective in 1992.^{3,4} The CLIA regulations set minimum federal standards based on the complexity of the testing performed, regardless of the location, type, or accreditation status of the laboratory.

The Centers for Medicare & Medicaid Services (CMS) oversees all clinical laboratory testing that is subject to the CLIA regulations, which require laboratories to be certified before they can accept human specimens for testing. CMS issues 4 types of CLIA certificates: Certificate of Accreditation (CoA), Certificate of Compliance (CoC), Certificate of Waiver (CoW), and Certificate for Provider Performed Microscopy Procedures (PPM). At the end of 2021, there were more than 320 000 CLIA-certified laboratories in all US states and territories (including those in the 2 CLIA-exempt states, New York and Washington), consisting of ~16 000 CoA, ~17 000 CoC, ~260 000 CoW, and ~31 000 PPM laboratories. CMS maintains data on CLIA-certified laboratories through the Quality Improvement and Evaluation System (QIES). CoA and CoC laboratories are certified to perform both waived and nonwaived (moderate and/or high complexity) testing and are subject to biennial inspection by accreditation organizations or state agency/CMS surveyors. During inspection, the information reported by the laboratory is verified by surveyors. The testing volume reported in QIES is assumed to be complete and accurate for all laboratories that perform nonwaived testing because test volumes are used to determine CLIA fees and inspectors verify test volumes when they conduct onsite inspections. Among the 7 CLIA-approved accreditation organizations, the College of American Pathologists (CAP) and COLA accredit the largest number of laboratories for CLIA purposes. CoA and CoC laboratories perform more than 90% of clinical tests, and 76% of these tests were performed by laboratories accredited by CAP or COLA. Information in QIES is self-reported by laboratories, including

the name and address, laboratory facility type, specialty(ies)/subspecialty(ies), and annual testing volume. Of the 29 laboratory facility types in QIES at the end of 2021, there were ~120 000 physician office, ~9000 hospital, and ~7000 independent laboratories in the United States.

Laboratory testing personnel data are frequently used to plan and design workforce development programs and for laboratory personnel management.⁵⁻⁷ An estimate of the number of CLIA testing personnel nationwide would be a useful resource, not only for these purposes, but also for the planning for public health emergencies. Most of the research conducted on CLIA laboratory personnel has been related to either personnel qualifications or workforce shortage.⁸⁻¹⁰ However, there are no published data on the numbers of CLIA laboratory testing personnel. The US Bureau of Labor Statistics (BLS) data capture the numbers of clinical laboratory technologists and technicians at the national and state level, but the BLS data do not break down the numbers by laboratory type. Therefore, it is not possible from BLS data to understand how testing personnel are distributed across the various types of laboratories or the volume of testing performed in each laboratory category. The laboratory personnel counts captured in QIES do not encompass all laboratory testing personnel, as data are only available on those who serve as laboratory directors, general supervisors, technical supervisors, clinical consultants, and technical consultants. Therefore, a data source in addition to QIES was needed in order to estimate the unreported total testing personnel. CAP and COLA collect more detailed laboratory personnel data from the laboratories in their respective accreditation programs than what are captured in QIES, since they include counts of testing personnel. This analysis focuses on deriving an estimate of total testing personnel in CoA and CoC laboratories. In doing so, we developed models to estimate missing testing personnel counts in QIES for all CoA and CoC laboratories, using CAP and COLA personnel data. Then we computed appropriate reliability statistics for the resultant stratified models by using a test volume per-person metric.

Current laboratory testing volume is the most direct indicator for assessing laboratory testing capacity, especially when planning for public health emergencies, such as the COVID-19 pandemic. During this pandemic, laboratory testing for SARS-CoV-2 was a critical part of the response, and laboratory testing personnel played an important role across the United States.^{11,12} The purpose of this study was to establish a statistical inference method using data from several sources (QIES, CAP, and COLA) to estimate the number of laboratory testing personnel by laboratory type and across states. The estimates from this study can be used to better understand clinical laboratory testing capacity across all laboratory types in order to support and strengthen public health emergency preparedness. When laboratory testing becomes a critical part of public health emergency response, the number of testing personnel and testing capacity across all types of testing sites are 2 important aspects to consider when it comes to resource planning and triage. In addition, the statistical methodology established in this study can be applied to local data for local laboratory testing personnel education and training needs. Similarly, the estimates on laboratory testing personnel across all testing sites and the estimates at the state or county level will provide bases to quantify the needs for educational opportunities and training resources in an effort to advance the practice of laboratory testing.

MATERIALS AND METHODS

QIES Database

The survey and certification data used for this analysis are reported to CMS for the administrative purpose of the CLIA program and were obtained from CMS QIES (<https://qtso.cms.gov/>). CLIA laboratory records can be linked across several data sets in QIES by the laboratory's CLIA identification number (ID). There were 33 033 CoA and CoC laboratories identified in the QIES data dated July 16, 2021, including those in the exempt states of New York and Washington. These CoA and CoC laboratories had complete data for test volume (including both waived and non-waived tests) and laboratory facility types. Besides the 3 facility types with the largest numbers of laboratories (hospital, independent, and physician office laboratories), there are 25 additional facility types for laboratories to select from when applying for CLIA certification listed in QIES, as well as "other." For this study, all facility types other than hospital, independent, and physician office were categorized as "other." All 29 laboratory facility types are listed in Supplemental Table 1 (see the supplemental digital content).

CAP and COLA Laboratory Personnel Data

In July 2021, CAP provided CDC with data for its 6405 CoA laboratories, including CLIA IDs and testing personnel counts for each CAP laboratory. These 6405 laboratories represented all CLIA-certified laboratories in the CAP accreditation program. COLA provided similar personnel data for 5667 CoA laboratories that receive CLIA accreditation from COLA. The general linear model showed no statistically significant difference in staff counts between the 2 data sets. Laboratory personnel other than testing personnel were excluded from the CAP and COLA data sets, and only testing personnel numbers were used for the analysis. CAP and COLA data sets were linked to QIES data by each laboratory's CLIA ID. Of the total CoA and CoC laboratories, CAP and COLA together provided testing personnel data for 12 072 CoA laboratories (36.5%).

Assumptions

The overall testing staff count from all CoA and CoC laboratories by July 2021 can be estimated, given the following assumptions:

1. We assume CoC laboratories have similar testing characteristics to CoA laboratories. Both CoC and CoA laboratories perform moderate- and high-complexity tests, are subject to biennial inspection, and are required to comply with CLIA regulations for nonwaived testing. The test methods and equipment are equally available to both CoA and CoC laboratories and similar market forces likely apply.
2. Since test volume per person varies by laboratory type and state, we assume that laboratories within the same laboratory facility type stratum that are accredited by organizations other than CAP and COLA (non-CAP/COLA laboratories) have similar test volumes per person as compared to CAP and COLA laboratories. Let P_{ijk} and V_{ijk} be the total number of personnel and the total number of annual test volume for k th non-CAP/COLA laboratory for i th laboratory type

($i = 1, 2, 3, 4$) located in j th state ($j = 1, \dots, 50$); we assume that $P_{ijk} = \beta_{ij}V_{ijk} + \varepsilon_{ijk}$, where β_{ij} is estimated from CAP/COLA laboratory data and ε_{ijk} is a random error. To further control possible outliers due to highly automated equipment in some laboratories, trimming at 95% of personnel to volume ratio at CAP/COLA laboratories and at 99% of testing volumes at non-CAP/COLA laboratories was applied during the estimation.

3. We also assume CAP and COLA laboratories are representative samples of all CoA and CoC laboratories. CAP and COLA laboratories constitute 56% (3747 of 6709) of hospital, 35% (1643 of 4632) of independent, 24% (3477 of 14 605) of physician office, and 34% (2377 of 7087) of other laboratories among all CoA and CoC laboratories. For test volume, CAP and COLA laboratories performed 80% (4 921 797 827 of 6 156 553 283), 85% (3 939 251 181 of 4 661 102 163), 55% (642 900 341 of 1 159 239 124), and 45% (579 247 000 of 1 286 867 283) of the total tests among all hospital, independent, physician office, and other CoA and CoC laboratories, respectively. The good representation of CAP and COLA data enables us to identify test volume as the most relevant indicator to correlate with personnel under this assumption.

Statistical Analysis and Estimation Methods

Under the above assumptions, with testing personnel data from the CAP and COLA data sets and test volume data from QIES data set, we aligned matching data by laboratory CLIA ID. The 33 033 CoA and CoC laboratories (including CAP and COLA laboratories) were stratified into 4 categories of laboratory facilities (hospital, independent, physician office, and other), as in Table 1 and Figure 1. For each stratum, the following analyses were performed. First, test volume per person was calculated with nonmissing personnel (which are CAP and COLA laboratories) and test volume at each stratification level. In this study, test volume per person refers to test volume per testing personnel, which does not include other laboratory staff such as the laboratory director and clinical consultant.

We treated CAP and COLA laboratories as representative samples, as if non-CAP/COLA data were missing at random¹³ and a simple random sampling (SRS) design was used in the model. Under this presumption, SRS statistics are valid in the estimation of testing personnel and the calculation of 95% CI for each stratum. We use $P_i = \sum_{j,k} P_{ijk}$ to estimate the total number of personnel for each laboratory category.

Estimate ratio (personnel [P]/test volume [V]) by using COLA and CAP data:

$$\text{Ratio} = \frac{\sum_{j,k} P_{ijk}}{\sum_{j,k} V_{ijk}}.$$

Calculate estimate standard error (SE) for laboratory personnel:

$$\text{SE}(P) = \sum_{j,k} V_{ijk} \times \text{SE}(\text{Ratio}).$$

Calculate 95% CI for the estimated testing personnel:

$$\sum_{j,k} P_{ijk} = \sum_{j,k} V_{ijk} \times \text{Ratio}.$$

$$95\% \text{ CI} = \sum_{j,k} P_{ijk} \pm 1.96 \times \text{SE}(P).$$

All computational work was conducted in SAS (version 9.4, SAS Institute, Cary, North Carolina) and SUDAAN (version 11.0.1, RTI International, Research Triangle Park, North Carolina).

The total estimate of testing personnel in CoA and CoC laboratories was compared with employment data reported by BLS for May 2021 under the category of “clinical laboratory technologists and technicians” (occupation code 29–2010) (https://www.bls.gov/oes/current/oes_nat.htm#29-0000). Data reported by BLS are considered real-world data.¹⁴ We also estimated the testing personnel in CoA and CoC laboratories in each of the 50 states and compared the counts with the employment of clinical laboratory technologists and technicians by state the BLS reported for May 2021 (<https://www.bls.gov/oes/current/oes292010.htm>).

Laboratory testing personnel was estimated by using the method above. Test volume, laboratory facility type, and laboratory counts were summarized from QIES. Test volume by facility type and by state was calculated. We also computed test volume ranges per person and per laboratory stratified by laboratory facility categories (Table 1). *P* values were calculated by pairwise comparison with Bonferroni corrections. We examined the distributions of the number of CoA and CoC laboratories, estimated total testing personnel, and annual test volume among the 4 laboratory facility types (Figure 1). The distribution of the number of CoA and CoC laboratories, estimated total testing personnel, and annual test volume by state were visualized in Figures 2 through 4.

RESULTS

Laboratory Testing Personnel Estimates

Based on our model, there were an estimated 328 287 (95% CI, 308 520–348 036) laboratory testing personnel who worked in CoA and CoC laboratories as of mid-2021 (Table 1). The BLS reported 318 780 for May 2021 for the category of clinical laboratory technologists and technicians, as shown in Table 2. Our estimation of total testing personnel in CoA and CoC laboratories is supported by the personnel data reported by BLS. In estimating non-CAP/COLA laboratory personnel, the ratio and SE were calculated for each state by each laboratory type. The random error ϵ_{ijk} is calculated to be 5181, which is 4.4% and 1.6% of the estimated non-CAP/COLA (116 704) and all CoA and CoC laboratory testing personnel (328 278), respectively. By using the laboratory type data in QIES, we estimated there were twice as many testing personnel who worked in hospital laboratories as in independent laboratories (158 778 versus 74 904, $P < .001$), and twice as many testing

personnel in independent laboratories as in physician office laboratories (74 904 versus 38 510, $P < .001$). There were more testing personnel who worked in other laboratories than independent laboratories (84 380 versus 74 904, $P < .001$).

The same statistical method was used to estimate laboratory testing personnel for each of the 50 states. The calculated results include the personnel estimate and 95% CI for each state. Figure 5 demonstrates how our estimates compared to the data reported by BLS. For most of the states, the BLS data (represented by the yellow symbol) fell within the 95% CI of the estimates, as indicated by the black whiskers. For some states, such as Illinois, Michigan, Missouri, Pennsylvania, and Wisconsin, testing personnel reported by BLS was higher than the upper limit of our estimates. For only 1 state, Nebraska, the BLS total was just below our lower bound.

Correlation of Numbers of Testing Personnel and Test Volume

By using the number of laboratories and annual test volume data from QIES, we were able to calculate the number of testing personnel per laboratory, test volume per laboratory, and test volume per person, as shown in Table 1. Annual test volume distribution is right skewed for each laboratory facility type category. Therefore, median test volume is lower than mean test volume. CAP and COLA laboratories have a good representation of all CoA and CoC laboratories by numbers, constituting 56% of hospital, 35% of independent, 24% of physician office, and 34% of other laboratories. Laboratories accredited by CAP and COLA had higher test volume than non-CAP/COLA laboratories. There were 56% (3747 of 6709), 35% (1643 of 4632), 24% (3477 of 14 605), and 34% (2377 of 7087) of hospital, independent, physician office, and other laboratories accredited by CAP or COLA and they performed 80% (4 921 797 827 of 6 156 553 283), 85% (3 939 251 181 of 4 661 102 163), 55% (642 900 341 of 1 159 239 124), and 45% (579 247 000 of 1 286 867 283) of the tests, respectively. The distributions of test volume among both CAP/COLA and non-CAP/COLA laboratories are right skewed, which is consistent with the skewness when they are combined. CAP and COLA laboratories' personnel data show a total of 211 574 testing personnel, which corresponds to about two-thirds of the total testing personnel estimated for all CoA and CoC laboratories. The total annual test volume from all CoA and CoC laboratories was calculated to be 13.3 billion, among which 10 billion tests were performed by CAP and COLA laboratories annually.

On average, there were more testing personnel who worked in each hospital laboratory than in each independent laboratory (24 versus 16, $P < .001$); however, independent laboratories were estimated to annually perform more tests per person on average than hospital laboratories' personnel (62 228 versus 38 775, $P < .001$). On average, there were more laboratory personnel who worked in hospitals than in physician office laboratories (24 versus 3, $P < .001$), and the number of tests performed annually per person was higher in hospital than physician office laboratories too (38 775 versus 30 102, $P < .001$). Testing personnel in independent laboratories performed almost twice as many tests on average annually per person as those in physician office laboratories (62 228 versus 30 102, $P < .001$), and physician office laboratory testing personnel performed twice as many tests on average annually per person as those in the other laboratory category (30 102 versus 15

251, $P < .001$). Independent laboratories had a higher number of tests per laboratory on an annual basis than hospital laboratories (1 006 283 versus 917 656, $P < .001$), and test volume per either independent or hospital laboratory was more than 10 times higher than physician office laboratory (917 656 of 1 006 283 versus 79 373, $P < .001$).

Among the 33 033 active CoA and CoC laboratories in the United States, as of mid-2021, the numbers of laboratories affiliated with hospital, independent, physician office, and other facility categories were 6708 (20%), 4631 (14%), 14 605 (44%), and 7087 (21%), respectively (Figure 1). However, the percentage of tests performed by each of these laboratory categories was not proportional to this distribution. For this study, as described above, we assumed that laboratories have similar operations within each facility type and that operations vary among the different facility types. Hospital and independent laboratories made up 20% and 14% of all CoA and CoC laboratories, respectively, but performed relatively larger portions of the laboratory tests, at 46% (6 156 553 283 of 13 263 761 853) and 35% (4 661 102 163 of 13 263 761 853), respectively, whereas physician office laboratories, 44% of all CoA and CoC laboratories, performed a comparatively low proportion of tests at 9% of total tests. The same disproportional pattern was observed for the laboratory testing personnel. Twenty-three percent of the laboratory testing personnel who worked in independent laboratories performed 35% of the total testing. However, 26% (84 380 of 328 278) of the laboratory testing workforce in the other facility type category performed only 10% (1 286 867 283 of 13 263 761 853) of the total testing. Independent laboratories had the highest test volume per person (Table 1). As shown in Figure 1, one-fifth of the CoA and CoC laboratories were hospital affiliated, and these laboratories perform almost half (46%) of all moderate- and high-complexity tests.

Distribution of Laboratories and Test Volume

Figure 2, A and B, shows the CoA and CoC laboratory distribution among the 50 US states. Figure 2, A, is the distribution of the number of laboratories, and Figure 2, B, is the number of laboratories normalized by the state population, that is, per 100 000 capita. Texas had the highest number of CoA and CoC laboratories among all states, followed by California and Florida. After normalization by state population, the pattern changed and South Dakota had the highest number of CoA and CoC laboratories per 100 000 capita, followed by Mississippi. For annual test volume in Figure 3, California ranked the top nationwide, followed by Texas and Florida. Figure 4, A and B, shows the estimated number of laboratory testing personnel in each state. In Figure 4, A, Texas had the highest number of testing personnel in the CoA and CoC laboratories, followed by California, New York, and Florida. When the numbers were normalized by state population, Utah was ranked number one among all 50 states: an estimated 148 testing personnel per 100 000 capita, as shown in Figure 4, B.

DISCUSSION

Laboratory personnel data are a valuable resource at both national and local levels in assessing the need for and the designing of clinical and public health laboratory training and workforce development programs. The quantitated laboratory testing personnel can

be compared and evaluated across all testing sites, as well as at state or county level, in order to provide adequate educational opportunities and training resources to improve the laboratory testing practice. When laboratory testing becomes critical as part of public health emergency response, the number of testing personnel and testing capacity are 2 important aspects to consider for resource planning and triage. Therefore, understanding total national laboratory testing capacity is also critical for public health emergency planning, especially considering the essential role that laboratory testing has played in responding to the COVID-19 pandemic.^{11,12}

The QIES database has records of supervisory personnel counts from moderate- and high-complexity testing. As mentioned earlier, those personnel counts include only the following positions in CLIA-certified CoA and CoC laboratories: laboratory director, general supervisor, technical supervisor, clinical consultant, and technical consultant. However, counts for testing personnel are not captured in QIES. Testing personnel are the largest component of the laboratory workforce. Fortunately, CAP and COLA CoA laboratory personnel data provided the missing piece of the personnel puzzle. About one-third of the CoA and CoC laboratories we studied are accredited for CLIA purposes by either CAP or COLA. By using CAP and COLA laboratories as representative samples, our estimation of the overall testing personnel in CoA and CoC laboratories is close to the employment counts for clinical laboratory technologists and technicians reported by BLS (Tables 1 and 2). The overall testing personnel and the estimates for each state are comparable to the BLS statistics (Figure 5). BLS collected employment data from a variety of laboratories, ranging from medical hospitals to outpatient care centers.¹⁵ Laboratory technologists and technicians reported by BLS may not be defined the same as the testing personnel that we estimated in this study, but we believe BLS covered all testing personnel in laboratories that perform moderate- and high-complexity tests. Therefore, our estimates are supported by the real-world data from BLS.

There are 2 assumptions in our methodology for the estimation. First, we assumed CoC laboratories have similar testing characteristics to CoA laboratories. The validity of this assumption relies on the fact that both CoC and CoA laboratories perform moderate- and high-complexity tests and both are required to comply with CLIA regulations for nonwaived testing, such as CLIA personnel rules and proficiency testing. The test methods and equipment are equally available to both CoA and CoC laboratories and similar market forces likely apply. This assumption allowed us to apply CAP and COLA data to all CoA and CoC laboratories when calculating our estimates. We also assumed all CoA and CoC laboratories, except those accredited by CAP and COLA in each stratum in the model, have the same test volume per person as CAP and COLA laboratories. To correlate the personnel in CAP and COLA laboratories to other CoA and CoC laboratories, it was necessary to identify some data-present indicator that is correlated with testing personnel. Test volume was the most appropriate indicator under the assumption that the test volume and testing personnel are proportional within the same self-designated laboratory type. The assumption behind this stratification is that all laboratory testing personnel generally can perform approximately the same number of tests per day, given the same equipment, the same test method, and the same laboratory type. This assumption is necessary to account for the dramatic difference in the number of tests performed in a high-throughput independent laboratory versus the

lower volume of tests performed in a physician office laboratory. Under this assumption, for example, personnel and test volume data in CAP and COLA hospital laboratories can be used to calculate personnel and test volumes for non-CAP/COLA hospital laboratories because test volume output per person is comparable across laboratories in the category of “hospital.” CAP and COLA laboratories performed unproportionally higher number of tests than non-CAP/COLA laboratories, as one-third of the CoA and CoC laboratories accredited by CAP and COLA performed 66% of the total tests.

As hospital laboratories perform the highest volume of testing among all CLIA laboratory types, much attention has been devoted to hospital-based clinical laboratories in terms of operational and financial performance.^{16,17} But the market also drives rapid high-throughput testing in large commercial laboratories that fall into the independent laboratory category.^{18–20} Our results showed that as a category, hospital laboratories had the highest annual test volume but not the highest test volume per testing personnel, while by category independent laboratories did not have the highest annual test volume but had the highest test volume per testing personnel. The difference in laboratory operations among different laboratory types allowed our development of estimates based on this output-per-person metric. Taking it a step further, test volume per testing personnel is an indicator of overall testing capacity of the laboratory. Therefore, using this metric, independent laboratories had the highest testing capacity among all types of CLIA-certified laboratories, followed by hospital laboratories and physician office laboratories. Our findings are consistent with the ad hoc COVID testing capacity reported by a few states.^{21,22} During the COVID-19 pandemic, large commercial laboratories were the main provider of SARS-CoV-2 molecular testing. On March 20, 2021, one of the large independent laboratories reported having capacity to perform more than 280 000 SARS-CoV-2 molecular diagnostic tests per day across all of its testing sites nationwide.²³ As of November 30, 2021, another large independent laboratory had performed 53.8 million SARS-CoV-2 molecular tests with a capacity of 275 000 molecular tests per day among all of its locations across the nation.²⁴

For the distribution of the number of CoA and CoC laboratories and testing personnel, it is not surprising to see that the states with large populations, such as California, Texas, New York, and Florida, have relatively larger numbers of laboratories and testing personnel than other states in the country (Figures 2 and 4). However, when the data are normalized by state population, the distribution patterns are different. The higher number of laboratories per capita that perform nonwaived tests in less populous states, such as South Dakota and Mississippi, may reflect the relative distribution of smaller hospital and commercial laboratories to serve the populations there. Testing personnel per capita was relatively higher for Utah and Minnesota than for other states. This may be explained by the fact that a national reference laboratory is located in Salt Lake City, Utah, and another large reference laboratory is located in Rochester, Minnesota. Unlike testing personnel, the test volume reported by CoA and CoC laboratories located in each state does not directly associate with the state population. We note that access to laboratory testing cannot always be directly correlated with laboratory locations in specific geographic locations. Specimens may be sent across state boundaries for testing, and individuals may have tests ordered and performed in locations other than their home state, whereas CoA and CoC laboratories were counted in the state where they were located in this analysis. For that reason, tests volumes reported

by laboratories in one state may not correlate with the population in that state. Therefore, test volume per capita was not calculated in Figure 3. In addition, as mentioned previously, the test volume by state is heavily influenced by the locations of several major reference laboratories, as they test specimens from across the United States or even internationally, rather than just from the states where they are located. In addition, Figures 2 through 4 provide information about CoA and CoC laboratories, which may be used as resources for surge capacity testing during public health emergencies. Even though some states have fewer CoA and CoC laboratories per capita than others, some CoA and CoC laboratories (ie, large commercial laboratories) provide testing services nationwide and they can triage or expand testing capacity to handle surging testing needs across the country in the event of disease outbreaks.

It would be ideal to estimate personnel in all CLIA-certified laboratories, including those with a CoW and a PPM certificate. However, contrary to CoA and CoC laboratories, CoW or PPM laboratories are not subject to routine inspection under CLIA. Consequently, the personnel information in CoW laboratories is not captured in the QIES database, nor is it captured by CAP or COLA. Therefore, we were not able to identify any data source to estimate testing personnel in CoW or PPM laboratories, and these were not part of our study results. Additional efforts are needed to collect the numbers of testing personnel in these other testing sites, especially since the number of testing personnel is likely significant given the large number of CoW laboratories (~260 000 by the end of 2021).

The findings in this report are subject to several limitations. First, we recognize that some testing personnel work in more than 1 laboratory, work part-time, or spend only part of a workday performing testing (the rest of workday performing other tasks), which our estimates do not account for. Second, the distribution of CAP and COLA laboratories may not be statistically representative nationwide. There may be more CAP and COLA laboratories in some states than others. CAP and COLA laboratories, as random samples at the national level, are not stratified at the state level. This may partially explain why the reported testing personnel count by BLS is higher than the upper limit of 95% CI in our estimates for some states. Third, our estimates only reflect testing personnel who were employed in CoA and CoC laboratories and may not include individuals who were qualified as laboratory testing personnel but did not work in this field or directly in these types of laboratories. Therefore, although these individuals are part of the clinical laboratory workforce, they might not be captured in our estimates. Finally, our assumption that CAP and COLA laboratories are representative samples of all CoA and CoC laboratories might underestimate or overestimate the total laboratory testing personnel owing to some unmeasurable factors. However, our assumption of similarity of personnel to test volume ratio between COLA and non-COLA laboratories only for the same laboratory type and the same state and application of trimming techniques could minimize the bias of estimation given the available data. Testing personnel data from CAP and COLA are the best and only data source available to us. For a more accurate estimation, future surveys are needed and testing personnel data from non-CAP/COLA laboratories need to be collected across all laboratory facility types. Furthermore, to obtain an overall picture on the testing personnel across all CLIA laboratories, innovative approaches are needed to estimate testing personnel for CoW and PPM laboratories.

CONCLUSIONS

In conclusion, our inference method has provided an estimate of the number of testing personnel in CoA and CoC laboratories that is corroborated by the BLS data. We propose that the test volume per-person metric by laboratory type can provide new insights for understanding the clinical laboratory landscape, which were previously unavailable. This study adds value to the CLIA laboratory data available to the public by illuminating testing personnel and test volume that will be useful in subsequent analyses including estimates at a geographic level other than state. For example, in addition to state code, QIES also provides the Health and Human Services region and Social Security Administration county code, which allows CLIA laboratories to be mapped accordingly. This will enable local governments to better evaluate and plan for clinical laboratory testing capacity in the event of public health emergencies, as well as to better understand CLIA laboratories' education and training needs.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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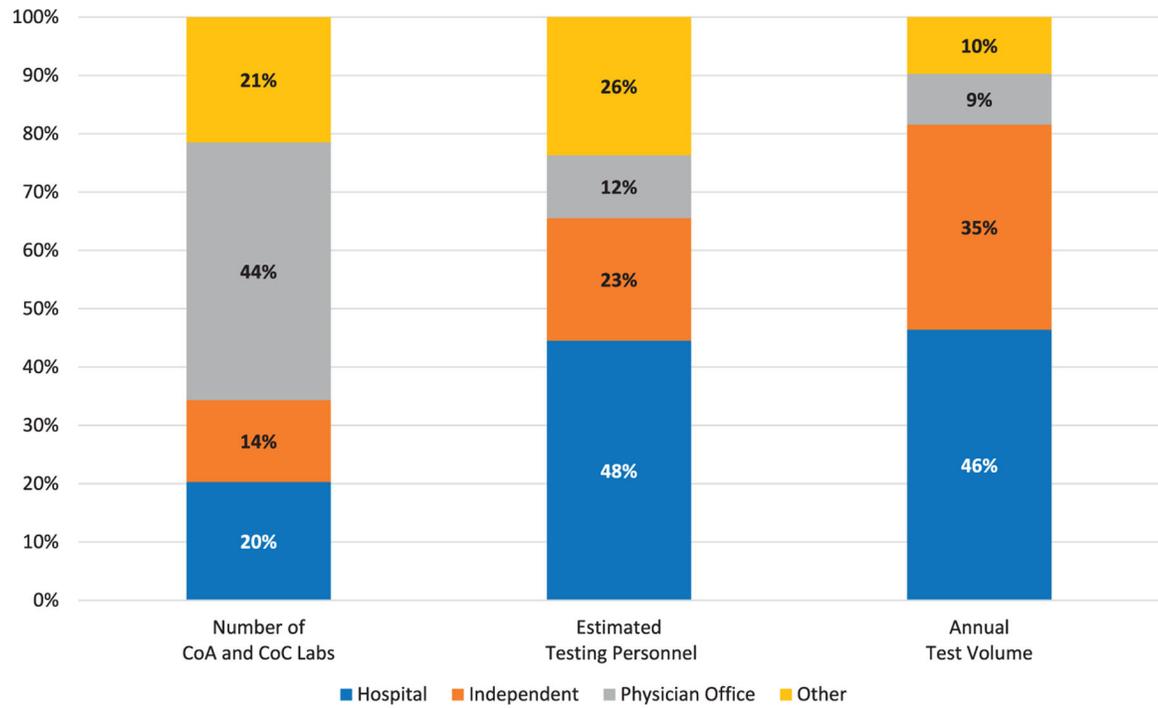


Figure 1. Number of laboratories, estimated laboratory testing personnel, and annual test volume distribution by facility category among Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) laboratories (2021).

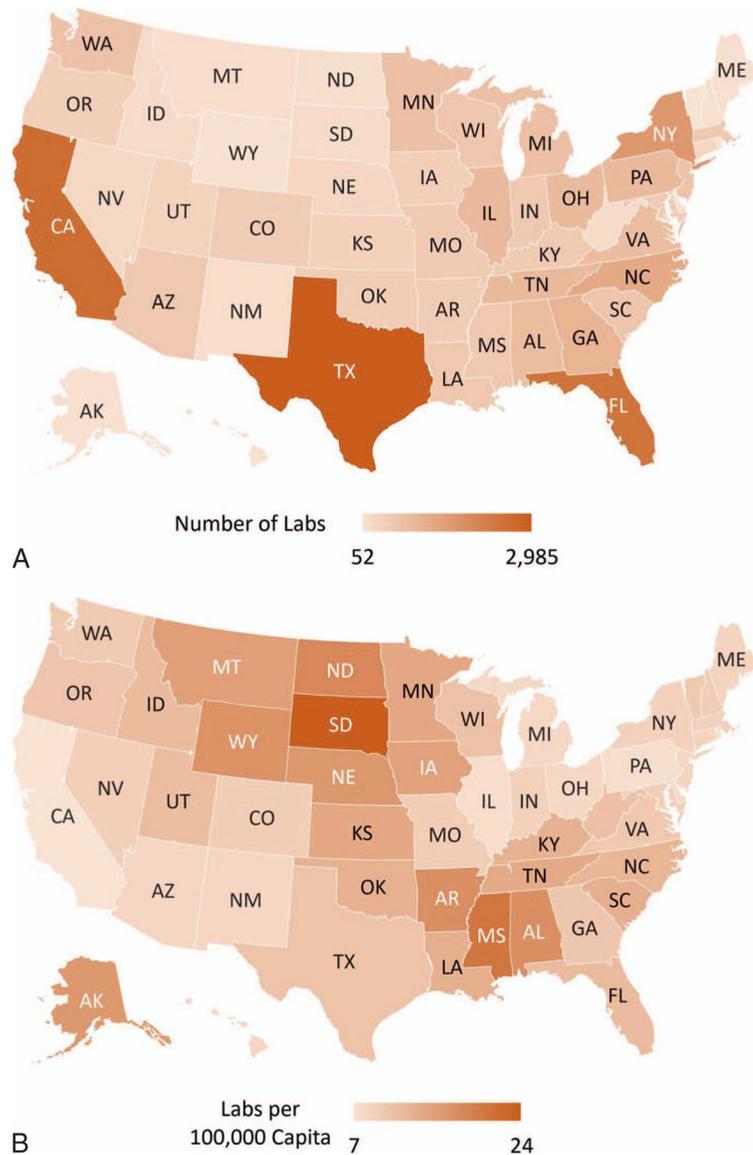


Figure 2. Certificate of Accreditation and Certificate of Compliance laboratory distribution in the United States (2021). A, Number of laboratories. B, Number of laboratories per 100 000 capita. The GeoNames geographical database is available for download free of charge under a Creative Commons attribution license (<https://creativecommons.org/licenses/by/4.0/>).

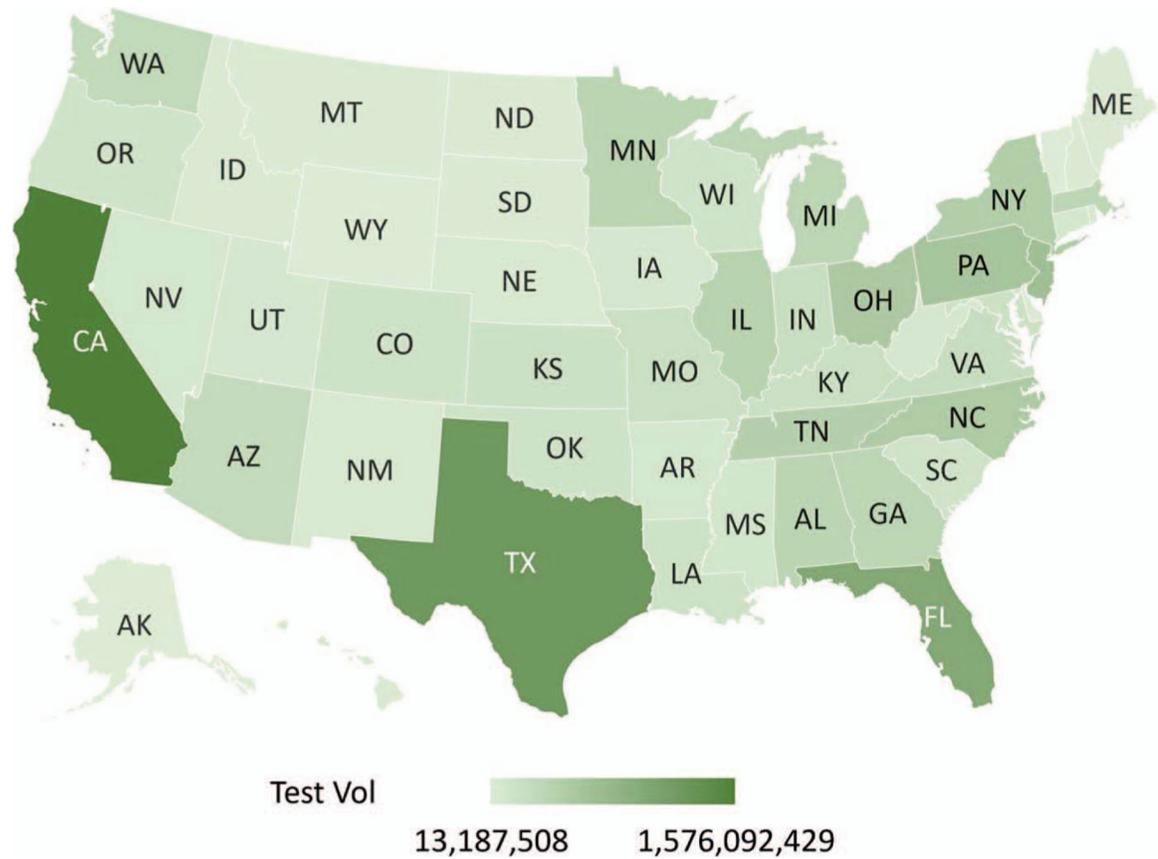


Figure 3. Certificate of Accreditation and Certificate of Compliance laboratory test volume (Vol) distribution in the United States (2021). The GeoNames geographical database is available for download free of charge under a Creative Commons attribution license (<https://creativecommons.org/licenses/by/4.0/>).

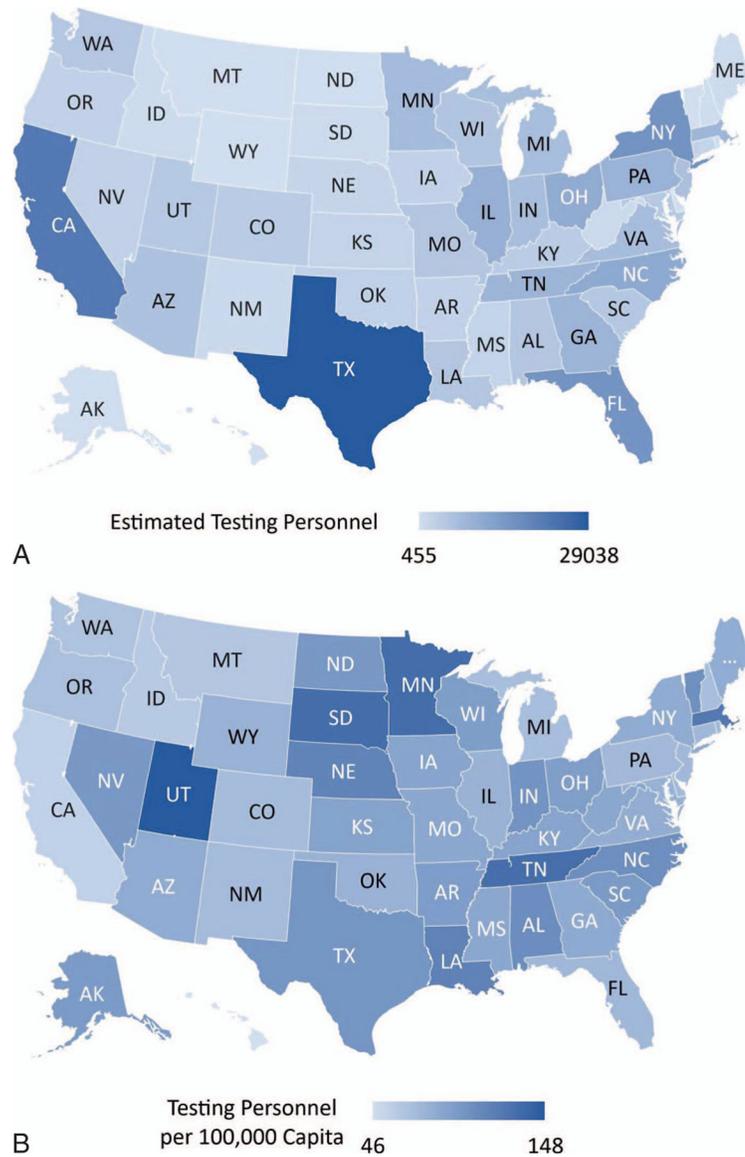


Figure 4. Estimated Certificate of Accreditation and Certificate of Compliance laboratory testing personnel distribution in the United States (2021). A, Estimated testing personnel. B, Estimated testing personnel per 100 000 capita. The GeoNames geographical database is available for download free of charge under a Creative Commons attribution license (<https://creativecommons.org/licenses/by/4.0/>).

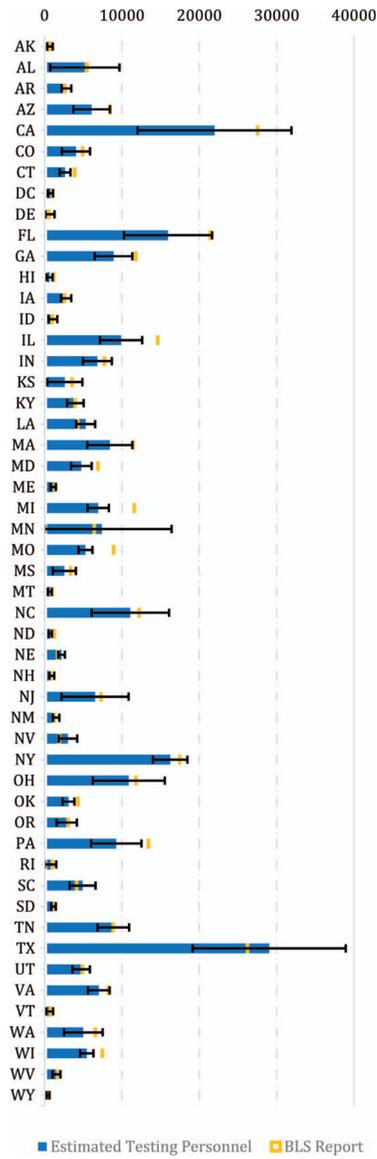


Figure 5. Estimated laboratory testing personnel for Certificate of Accreditation and Certificate of Compliance laboratories among 50 states versus US Bureau of Labor Statistics (BLS) occupational employment data.

Table 1.

Estimated Numbers of Laboratory Testing Personnel for Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) Laboratories (2021)

Laboratory Facility Type	Number of CoA and CoC Laboratories	Estimated Numbers of Testing Personnel (95% CI)	Annual Test Volume/Laboratory Type	Annual Test Volume, Mean	Annual Test Volume, Median (P25, P75)	Estimated Number of Testing Personnel/Laboratory (95% CI)	Estimated Test Volume/Testing Personnel (95% CI)
Hospital	6709	158 778 (152 503–165 053)	6 156 553 283	917 656	298 392 (62 000, 990 359)	24 (23, 25)	38 775 (37 300, 40 370)
Independent	4632	74 904 (67 139–82 669)	4 661 102 163	1 006 283	25 000 (4063, 156 276)	16 (14, 18)	62 228 (56 383, 69 425)
Physician office	14 605	38 510 (36 215–40 805)	1 159 239 124	79 373	9999 (1833, 36 360)	3 (2, 3)	30 102 (28 409, 32 010)
Other	7087	84 380 (73 560–95 200)	1 286 867 283	181 581	14 853 (2300, 78 904)	12 (10, 13)	15 251 (13 518, 17 494)
Total	33 033	328 278 (308 520–348 036)	13 263 761 853	401 531	20 711 (3060, 132 756)	10 (9, 11)	40 404 (38 110, 42 992)

Abbreviations: P25, 25th percentile; P75, 75th percentile.

The Report on Employment for Clinical Laboratory Technicians and Technologists by the US Bureau of Labor Statistics.^a

Table 2.

Occupation Code	Occupation Title	Level	Employment	Employment RSE	Employment per 1000 Jobs	Median Hourly Wage	Mean Hourly Wage	Annual Mean Wage	Mean Wage RSE
29-2010 ^b	Clinical Laboratory Technologists and Technicians	Broad	318 780	0.8%	2.263	\$27.79	\$27.36	\$56,910	0.3%

Abbreviation: RSE, relative standard error.

^aUS Bureau of Labor Statistics, May 2021 National Occupational Employment and Wage Estimates.

^bhttp://www.bls.gov/oes/current/oes_nat.htm#29-0000.